UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,837	10/18/2001	Nabil G. Seidah	480848.9002	3590

7590 02/26/2003

Jean C Baker
Quarles & Brady
Suite 2550
411 East Wisconsin Avenue
Milwaukee, WI 53202-4497

EXAMINER
MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/830,837	Applicant(s) SEIDAH ET AL.	
	Examiner William W. Moore	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *30-83* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

Applicant's Amendment C, Paper No. 13 filed August 26, 2002, has been entered and the new claims 30-83 now replace the canceled claims 1-29. Despite an occasional recitation of an incomplete sentence, e.g., claims 34, 46, and 50, the presentation of a series of non-statutory claims, i.e., claims 57, 60-64 and 66, and a recited dependency from a cancelled claim in claim 46, most claims presented in the amendment have, in order to advance the prosecution of the instant application, been included in the following requirement for restriction as though they had been written to clearly describe an intended invention, to state a dependency from a pending claim, and as though they had been drafted to comply with 35 U.S.C. §101. Thus the reference to the cancelled claim 3 in claim 46 is considered to be a typographical error where a similar clause in claim 47 suggests that claim 46 had been intended to refer to claim 32, and clauses (4) of claims 46 and 47 indicate that claim 32 was intended to describe a "complex". However, claims 58, 59, and 76-79, cannot be included in the requirement for restriction, and are not otherwise treated herein, where no latent intent can be ascertained because the subject matters they describe cannot be identified as pertaining to the claims from which these claims recite a dependency.

Election/Restrictions

Restriction is required under 35 U.S.C. §§121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 30-31, 33, 36-46, 65, 67-75 and 80-83, drawn, in part, to a first product which is either a catalytic fragment of a rat SKI-1 having the

amino acid sequence set forth in SEQ ID NO:2 from position 187 through 996, inclusive, or to an inhibitory fragment of a rat SKI-1, having the amino acid sequence set forth in SEQ ID NO:2 from position 18 through 137, inclusive, to a first method of making a catalytic fragment of a rat SKI-1 using a host cell comprising and expressing a nucleic acid sequence encoding the catalytic fragment, to vectors and host cells comprising the encoding nucleic acid sequence useful in the method, and to a first method of use of a catalytic of a rat SKI-1 in cleaving an SKI-1 substrate, classified, *inter alia*, in class 530, subclass 350.

Group 2, claims 30-31, 33, 36-46, 65, 67-75 and 80-83, drawn, in part, to a second product which is either a catalytic fragment of a murine SKI-1, having the amino acid sequence set forth in SEQ ID NO:4 from position 187 through 996, inclusive, or to an inhibitory fragment of a murine SKI-1, having the amino acid sequence set forth in SEQ ID NO:4 from position 18 through 137, inclusive, to a first method of making a catalytic fragment of a murine SKI-1 using a host cell comprising and expressing a nucleic acid sequence encoding the catalytic fragment, to vectors and host cells comprising the encoding nucleic acid sequence useful in the method, and to a first method of use of a fragment of a murine SKI-1 in cleaving an SKI-1 substrate, classified, *inter alia*, in class 530, subclass 350.

Group 3, claims 30-31, 33, 36-46, 65, 67-75 and 80-83, drawn, in part, to a third product which is either a catalytic fragment of a human SKI-1, having the amino acid sequence set forth in SEQ ID NO:6 from position 187 through 996, inclusive, or to an inhibitory fragment of a human SKI-1, having the amino acid sequence set forth in SEQ ID NO:6 from position 18 through 137, inclusive, to a first method of making a catalytic fragment of a human SKI-1 using a host cell comprising and expressing a nucleic acid sequence encoding the catalytic fragment, to vectors and host cells comprising the encoding nucleic acid sequence useful in the method, and to a first method of use of a fragment of a human SKI-1 in cleaving an SKI-1 substrate, classified, *inter alia*, in class 530, subclass 350.

Group 4, claims 32 and 46, drawn to a fourth product which is a complex of an amino-proximal fragment of an SKI-1 amino acid sequence and another SKI-1 molecule lacking a signal peptide, and to a first method of use thereof in cleaving an SKI-1 substrate, classified, *inter alia*, in class 530, subclass 350.

Group 5, claim 47, drawn to a second use of the fourth product, which is a complex of an amino-proximal fragment of an SKI-1 amino acid sequence and another SKI-1 molecule lacking a signal peptide, in producing a desired

protein or peptide by cleaving a precursor polypeptide, classified, *inter alia*, in class 530, subclass 350.

Group 6, claims 34, 35, 70 and 71, drawn to a fifth product which is a modified SKI-1 amino acid sequence capable of preventing an enzymatic process in a cell wherein the modified SKI-1 is expressed, classified, *inter alia*, in class 530, subclass 350.

Group 7, claims 47-49 and 66, drawn to a second method of use of the first product, a catalytic fragment of a rat SKI-1, in producing a desired protein or peptide by cleaving a precursor polypeptide, classified, *inter alia*, in class 435, subclass 68.1.

Group 8, claims 47-49 and 66, drawn to a second method of use of the second product, a catalytic fragment of a murine SKI-1, in producing a desired protein or peptide by cleaving a precursor polypeptide, classified, *inter alia*, in class 435, subclass 68.1.

Group 9, claims 47-49 and 66, drawn to a second method of use of the third product, a catalytic fragment of a human SKI-1, in producing a desired protein or peptide by cleaving a precursor polypeptide, classified, *inter alia*, in class 435, subclass 68.1.

Group 10, claim 50, drawn, in part, to a third method of use of the first product, an inhibitory fragment of a rat SKI-1, in inhibiting the activity of an SKI-1 isoenzyme, classified, *inter alia*, in class 514, subclass 2.

Group 11, claim 50, drawn, in part, to a third method of use of the second product, an inhibitory fragment of a murine SKI-1, in inhibiting the activity of an SKI-1 isoenzyme, classified, *inter alia*, in class 514, subclass 2.

Group 12, claim 50, drawn, in part, to a third method of use of the third product, an inhibitory fragment of a human SKI-1, in inhibiting the activity of an SKI-1 isoenzyme, classified, *inter alia*, in class 514, subclass 2.

Group 13, claim 50, drawn, in part, to a first method of use of a sixth product, a nucleotide complementary to a rat SKI-1-encoding nucleic acid in inhibiting the activity of an SKI-1 isoenzyme, classified, *inter alia*, in class 536, subclass 24.5.

Group 14, claim 50, drawn, in part, to a first method of use of a seventh product, a nucleotide complementary to a murine SKI-1-encoding nucleic acid in inhibiting the activity of an SKI-1 isoenzyme, classified, *inter alia*, in class 536, subclass 24.5.

Group 15, claim 50, drawn, in part, to a first method of use of an eighth product, a nucleotide complementary to a human SKI-1-encoding nucleic acid

in inhibiting the activity of an SKI-1 isoenzyme, classified, *inter alia*, in class 536, subclass 24.5.

Group 16, claims 51-57 and 60, drawn to a ninth product, a peptide of at least seven amino acids, and to a first method of use of the peptide in monitoring the activity of an SKI-1 isoenzyme, classified in class 530, subclass 300.

Group 17, claim 61, drawn to a second method of use of the ninth product, a peptide of at least seven amino acids, in assays to detect inhibitors or substrates of an SKI-1 isoenzyme, classified in class 435, subclass 4.

Group 18, claims 62-64, drawn, in part, to a fourth method of use of the first product, an inhibitory fragment of a rat SKI-1, in a method of preparing a medication for treatment of disease involving overexpression of an SKI-1 isoenzyme or a substrate of an SKI-1 isoenzyme, classified in class 435, subclass 4.

Group 19, claims 62-64, drawn, in part, to a fourth method of use of the second product, an inhibitory fragment of a murine SKI-1 in a method of preparing a medication for treatment of disease involving overexpression of an SKI-1 isoenzyme or a substrate of an SKI-1 isoenzyme e, classified in class 435, subclass 4.

Group 20, claims 62-64, drawn, in part, to a fourth method of use of the third product, an inhibitory fragment of a human SKI-1 in a method of preparing a medication for treatment of disease involving overexpression of an SKI-1 isoenzyme or a substrate of an SKI-1 isoenzyme, classified in class 435, subclass 4.

The inventions listed as Groups I, 2 and 3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the rat, murine, and human SKI-1 products has a different, specific, primary structure, thus cannot share a same special technical feature.

The inventions listed as Groups 7, 8 and 9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the rat, murine, and human SKI-1 products has a different, specific, primary structure, thus the methods of the inventions cannot share a same special technical feature.

The inventions listed as Groups 10, 11 and 12 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the rat, murine, and human SKI-1 products has a different, specific, primary structure, thus the methods of the inventions cannot utilize products sharing a same special technical feature.

The inventions listed as Groups 13, 14 and 15 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the polynucleotides complementary to a nucleic acid sequence which encodes a rat, murine, or human SKI-1 products and that is required for use in methods of the inventions of Groups 13, 14 and 15 has a different, specific, nucleotide sequence, thus cannot share a same special technical feature.

The inventions listed as Groups 18, 19 and 20 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the rat, murine, and human SKI-1 products has a different, specific, primary structure, thus the methods of the inventions cannot utilize products sharing a same special technical feature.

The inventions listed as Groups I-3 and the inventions listed as Groups 7-12 and 18-20 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Methods of use of rat, murine, and human SKI-1 products in cleaving some native SKI-1 substrates, may not be practiced, as claimed, with methods of Groups 7-9 for cleaving precursor polypeptides because the precursors are not required to share any structural relationship with native SKI-1 substrates, and because methods of use of rat, murine, and human SKI-1 products in cleaving SKI-1 substrates cannot be practiced

with methods of Groups 10-12 of inhibiting SKI-1 activity and methods of Groups 18-20 of preparing medications, thus the disparate inventions cannot share a same special technical feature.

The inventions listed as Groups 7-9 and the inventions listed as Groups 10-12 and 18-20 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Methods of use of rat, murine, and human SKI-1 products in cleaving precursor polypeptides cannot be practiced with methods of Groups 10-12 of inhibiting SKI-1 activity and methods of Groups 18-20 of preparing medications, thus the disparate inventions cannot share a same special technical feature.

The inventions listed as Groups 10-12 and the inventions listed as Groups 18-20 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Methods of use of rat, murine, and human SKI-1 products of inhibiting SKI-1 activity cannot be practiced concurrently with methods of Groups 18-20 preparing medications, thus the disparate inventions cannot share a same special technical feature.

The inventions listed as Groups 13-15 and the inventions listed as Groups 1-3, 7-12 and 18-20 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Methods of use of polynucleotides complementary to nucleic acid sequences encoding rat, murine, and human SKI-1 products in inhibiting the cellular translation of the products are incompatible with methods of Groups 1-3 of cleaving SKI-1 substrates and incompatible as well with methods of Groups 7-9 for cleaving precursor polypeptides, and because methods of use of polynucleotides complementary to nucleic acid sequences encoding rat, murine, and human SKI-1

products in inhibiting translation of these products cannot be practiced with methods of Groups 10-12 of inhibiting SKI-1 activity with a peptide product and cannot be practiced with methods of Groups 18-20 of preparing medications, thus the disparate inventions cannot share a same special technical feature.

The inventions listed as Groups I-3, 7-12 and 18-20 and the inventions listed as Groups 4 and 5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the rat, murine, and human SKI-1 products has a different primary structure but complexes of Groups 4 and 5 require no particular SKI-1 components, thus cannot share a technical feature which is special with products or methods of inventions of Groups 1-3, 7-12 and 18-20.

The inventions listed as Groups 13-15 and the inventions listed as Groups 4 and 5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Methods of use of polynucleotides complementary to nucleic acid sequences encoding rat, murine, and human SKI-1 products in inhibiting translation of these products cannot be practiced with complexes of Groups 4 and 5 thus the disparate inventions cannot share a same special technical feature.

The inventions listed as Groups 4 and 5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Methods of use of complexes of non-specific SKI-1 products in cleaving some native SKI-1 substrates of Group 4, may not be practiced, as claimed, with a method of Group 5 for cleaving precursor polypeptides because the precursors are not required to share any structural

relationship with native SKI-1 substrates, thus the disparate inventions cannot share a same special technical feature.

The inventions listed as Groups I-3, 7-12 and 18-20 and the invention of Group 6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the rat, murine, and human SKI-1 products has a specific, defined, primary structure but the variant SKI-1 product of Group 6 has no specific structure and cannot constitute a rat, murine, or human SKI-1 product thus cannot share a same special technical feature with inventions of Groups 1-3, 7-12 and 18-20.

The inventions listed as Groups I3-15 and as Group 6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Methods of use of polynucleotides complementary to nucleic acid sequences encoding rat, murine, and human SKI-1 products in inhibiting translation of these products cannot be practiced variant SKI-1 products of Group 6, thus the disparate inventions cannot share a same special technical feature.

The inventions listed as Groups I-3, 7-12 and 18-20 and as Groups 16 and 17 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the rat, murine, and human SKI-1 products has a different, specific, primary structure but peptides of Groups 16 and 17 cannot constitute any particular SKI-1 product, thus cannot share a same special technical feature with inventions of Groups 1-3, 7-12 and 18-20.

The inventions listed as Groups I3-15 and as Groups 16 and 17 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2,

they lack the same or corresponding special technical features for the following reasons: Methods of use of polynucleotides complementary to nucleic acid sequences encoding rat, murine, and human SKI-1 products in inhibiting translation of these products cannot be practiced with peptides of Groups 16 and 17, thus the disparate inventions cannot share a same special technical feature.

The inventions listed as Groups 16 and 17 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The methods of Group 16, as claimed, is incapable of concurrent practiced with a method of Group 17, as claimed, thus the disparate inventions cannot share a same special technical feature.

The inventions listed as Groups 4 and 5 and the invention of Group 6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Complexes of SKI-1 products required by invention of Groups 4 and 5 are not required to have components wherein variations of the amino acid sequence of a native SKI-1 product occur, but the invention of Group 6 requires that a variant SKI-1 product have an amino acid sequence that differs from that of a native SKI-1 product, thus the disparate inventions cannot share a same special technical feature.

The inventions listed as Groups 4 and 5 and the inventions listed as Groups 16 and 17 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Complexes of SKI-1 products required by invention of Groups 4 and 5 cannot be peptides having a structure of a peptide of the inventions of Groups 16 and 17, thus the disparate inventions cannot share a same special technical feature.

The invention of Group 6 and the inventions listed as Groups 16 and 17 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The modified SKI-1 amino acid sequence required by the invention of Group 6 cannot be a peptide having a structure of a peptide of the inventions of Groups 16 and 17, thus the disparate inventions cannot share a same special technical feature.

A telephone call was made to Ms. Jean C. Baker on February 10, 2003, to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 9:00AM-5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. Further fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. The examiner's direct FAX telephone number is 703.746.3169. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
February 10, 2003